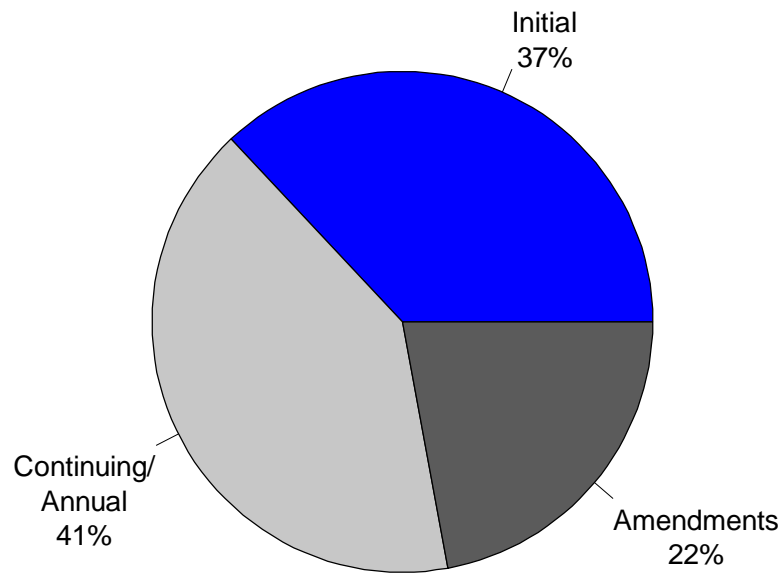


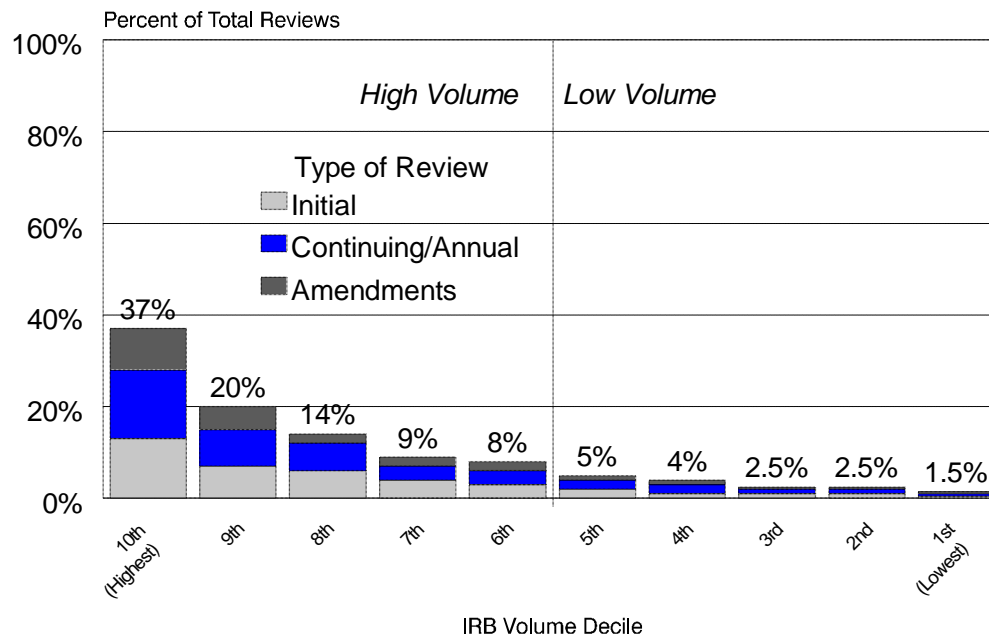
Figure 1
Distribution of IRB Reviews by Type



Total Reviews = 284,000

Source: IRB Chair Questions C12-C14 (n = 394); NIH Study of Human Subjects Protection

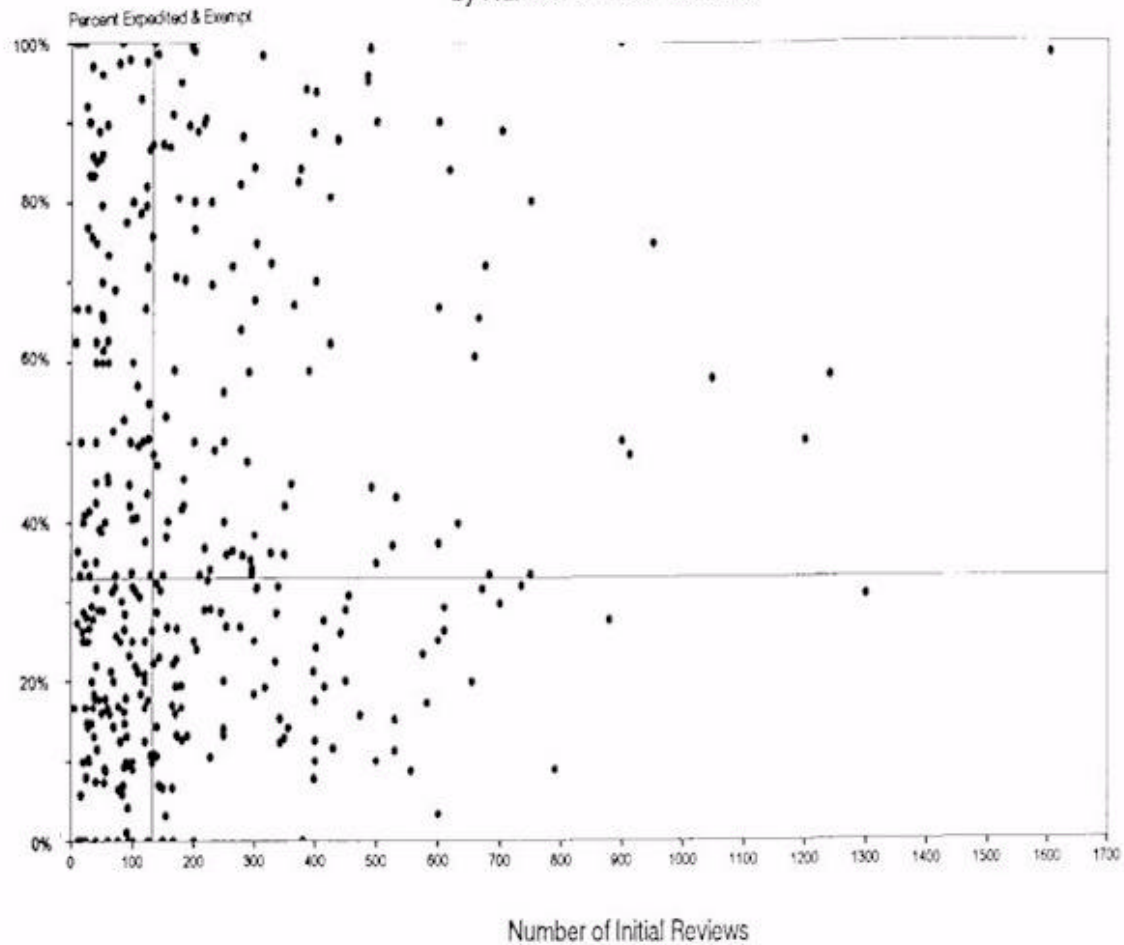
Figure 2
Percentage of Total Reviews
By Volume Decile



Source: IRB Chair Questions C12-C14 (n = 394); NIH Study of Human Subjects Protection
 N = 284,000 initial, continuing/annual, and amendment reviews

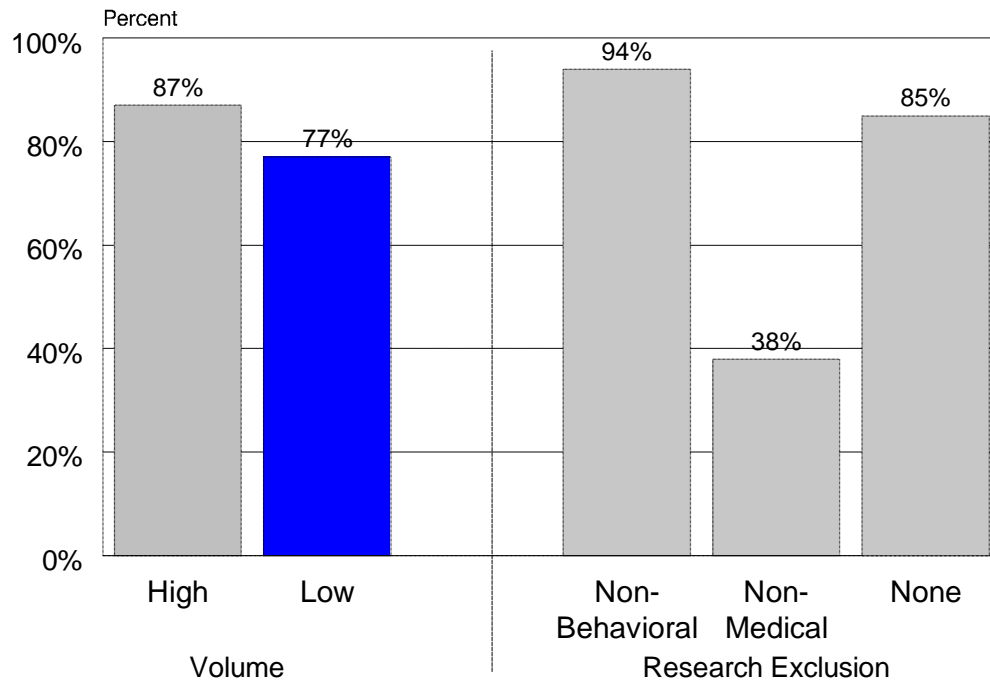
Figure 3

Percent Expedited Initial Reviews and Exempt Protocols
by Number of Initial Reviews



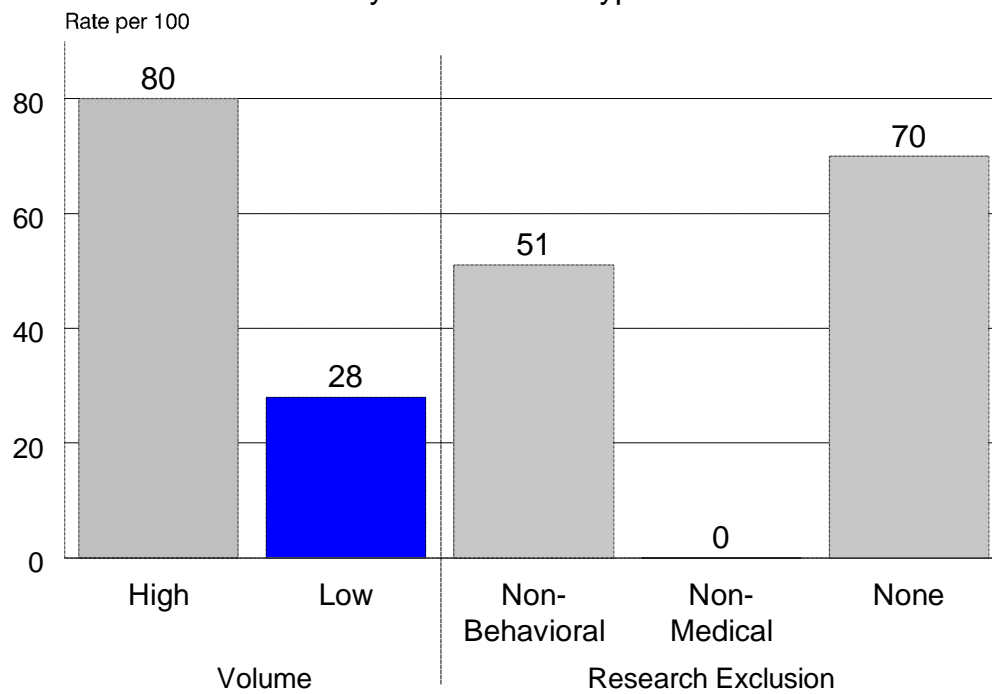
Source: IRB Chair Questions C12-C14 (n = 394); NIH Study of Human Subjects Protection

Figure 4
Percent of IRBs that Reviewed Any Multicenter Research Protocols
By Volume/Type of IRB



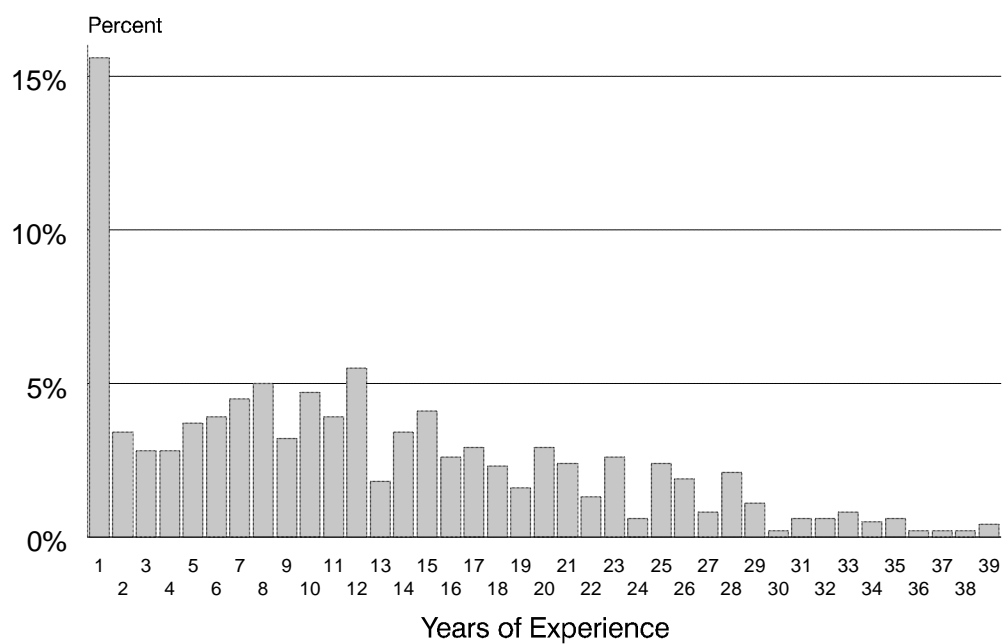
Source: IRB Chair Question C20 (n = 394); NIH Study of Human Subjects Protection

Figure 5
Out of Jurisdiction Harms Reports per 100 Initial Reviews
by IRB Volume/Type



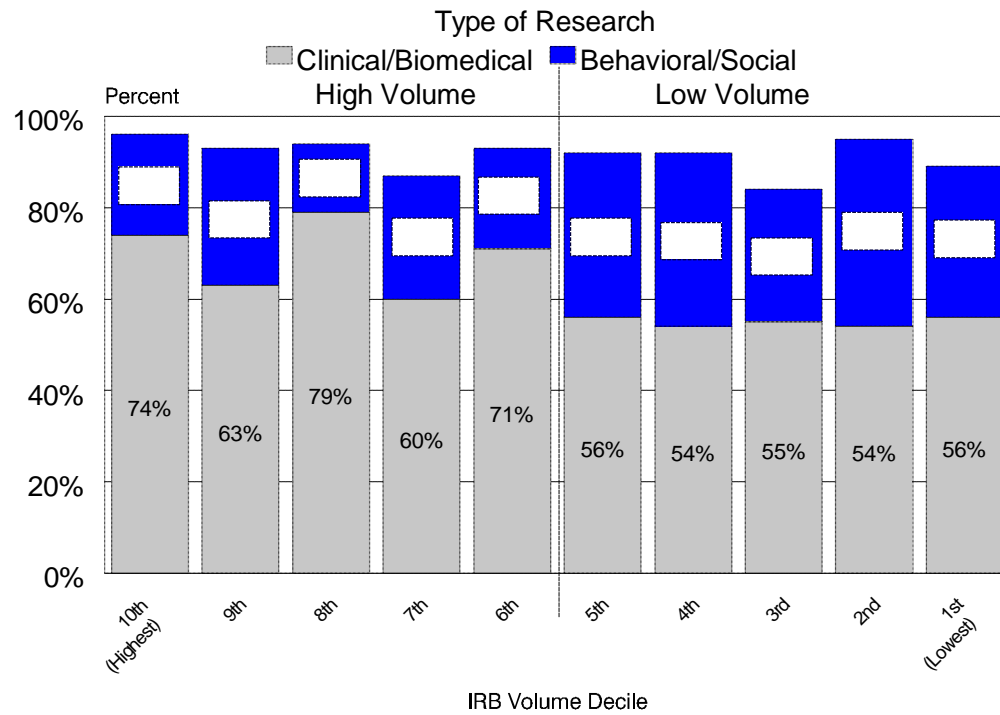
Source: IRB Chair Question C27 (n = 394); NIH Study of Human Subjects Protection

Figure 6
Investigator Years of Experience in Human Subjects Research



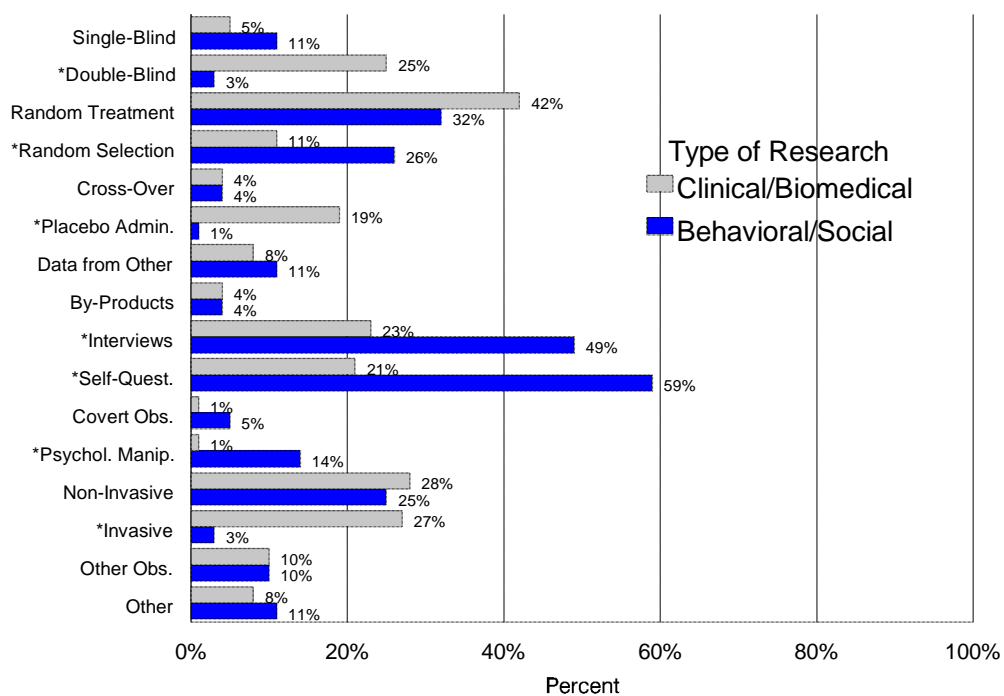
Source: IRB Investigator Question A3 (n = 632); NIH Study of Human Subjects Protection

Figure 7
Proportion of Type of Research by IRB Volume Decile



Source: Investigator Question B17 (n = 632): NIH Study of Human Subjects Protection

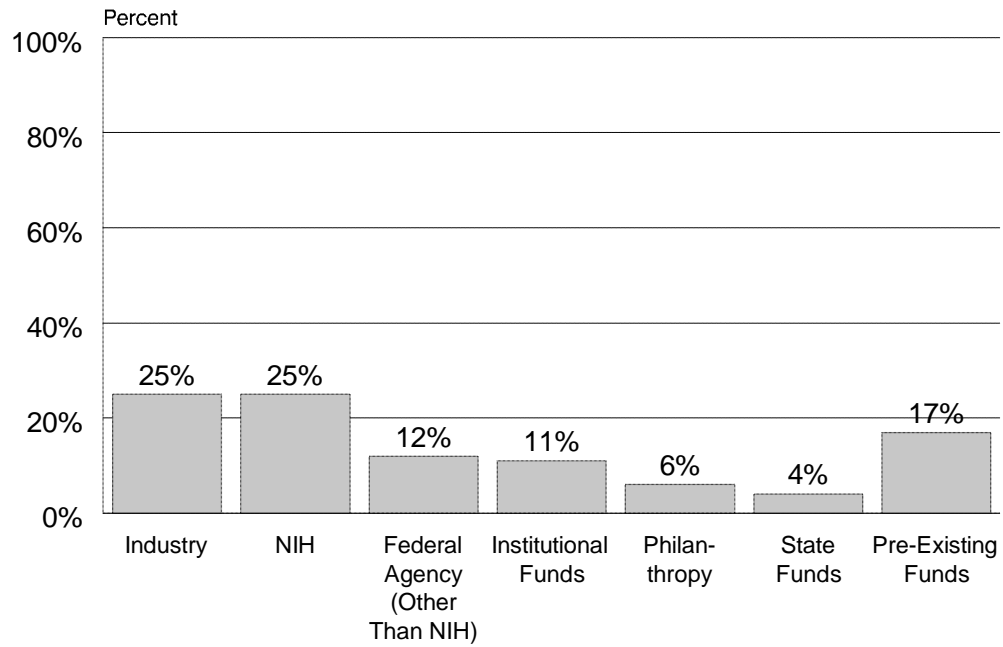
Figure 8
Methods Used in Protocols by Type of Research



Source: Investigator Question B18 (n = 632); NIH Study of Human Subjects Protection

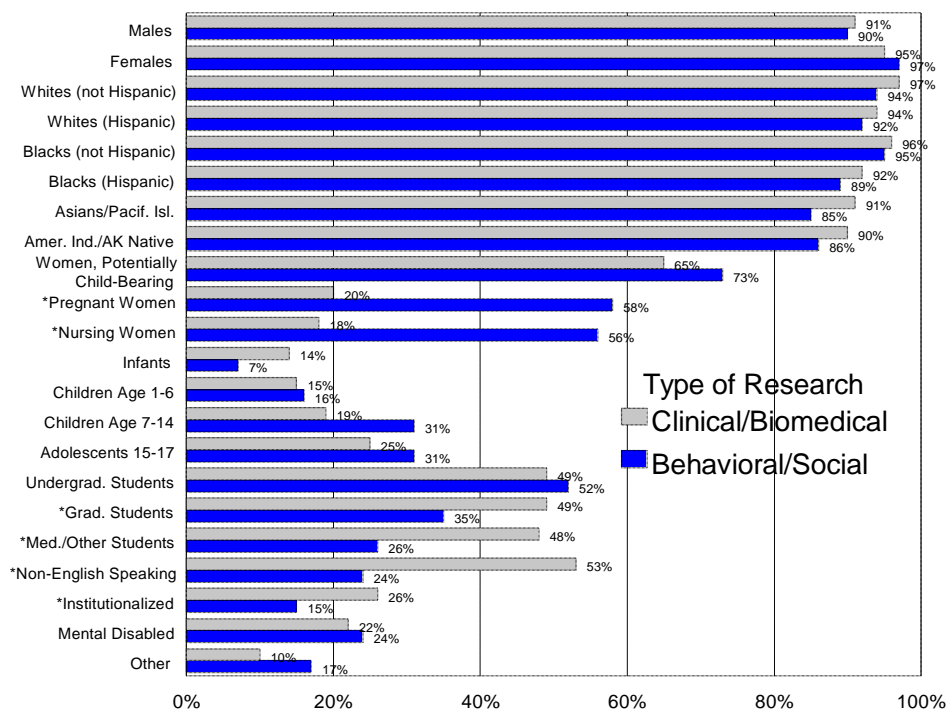
* denotes statistically significant differences at the .05 level

Figure 9
Sources of Funds for Implemented Protocols Reviewed by the IRB



Source: IRB Chair Question C40 (n = 394); NIH Study of Human Subjects Protection

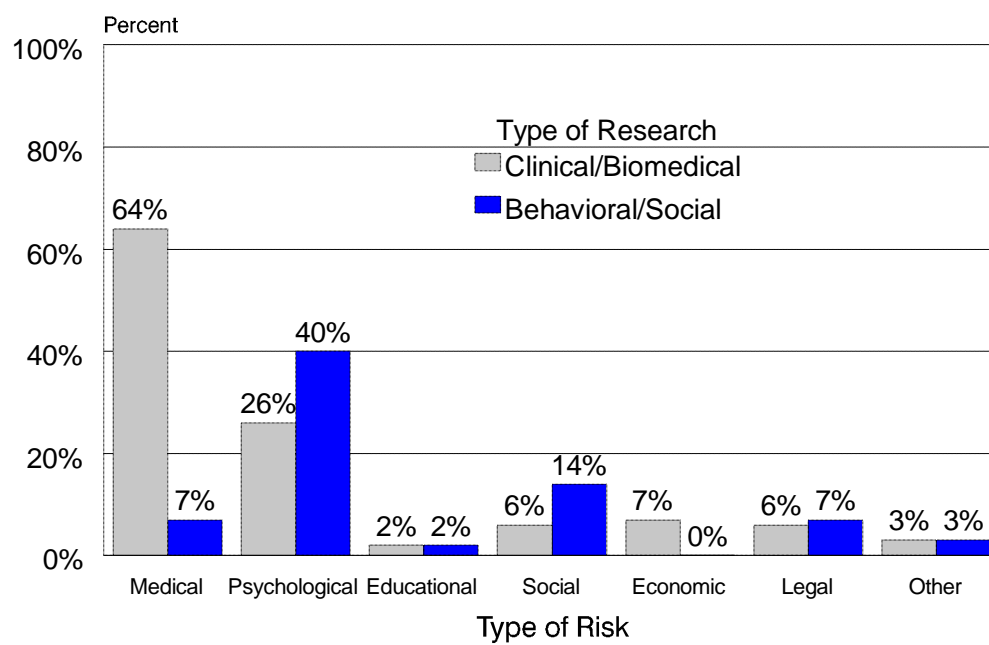
Figure 10
Human Subjects Eligible for Participation in Studies by Type of Research



Source: Investigator Question B21 (n = 632); NIH Study of Human Subjects Protection

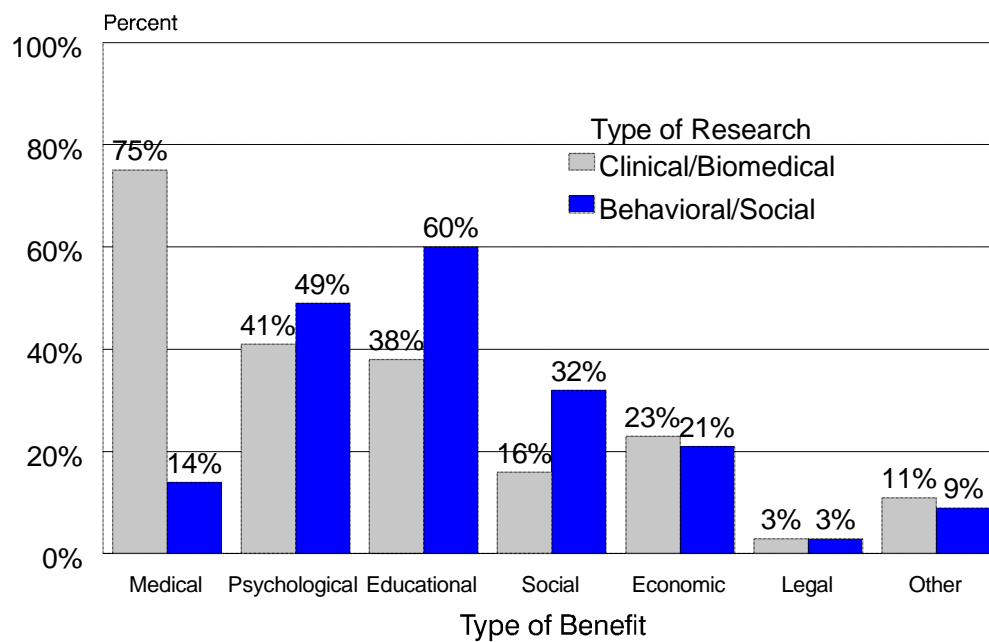
* denotes statistically significant differences at the .05 level

Figure 11a
Risks Anticipated to Subjects by Type of Risk and Type of Research



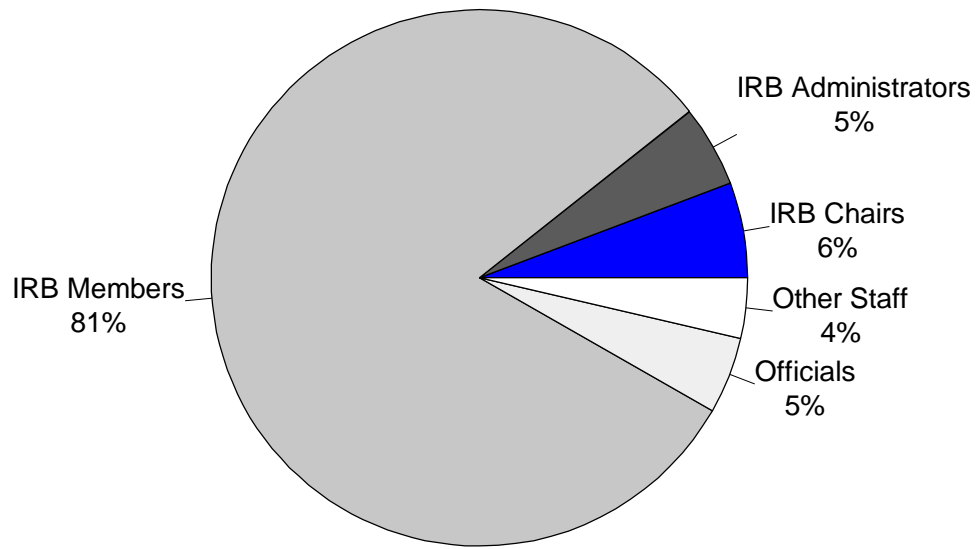
Source: Investigator Question B7 (n = 632); NIH Study of Human Subjects Protection

Figure 11b
Benefits Anticipated to Subjects by Type of Benefit and Type of Research



Source: Investigator Question B6 (n = 632); NIH Study of Human Subjects Protection

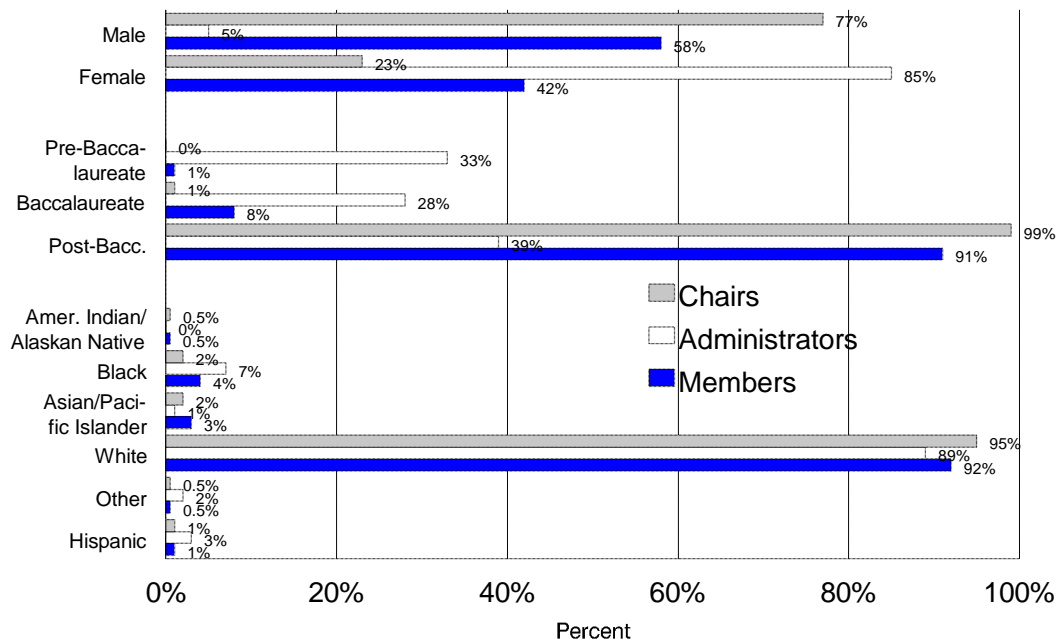
Figure 12
Distribution of IRB Personnel by Category



Total Persons = 8,414

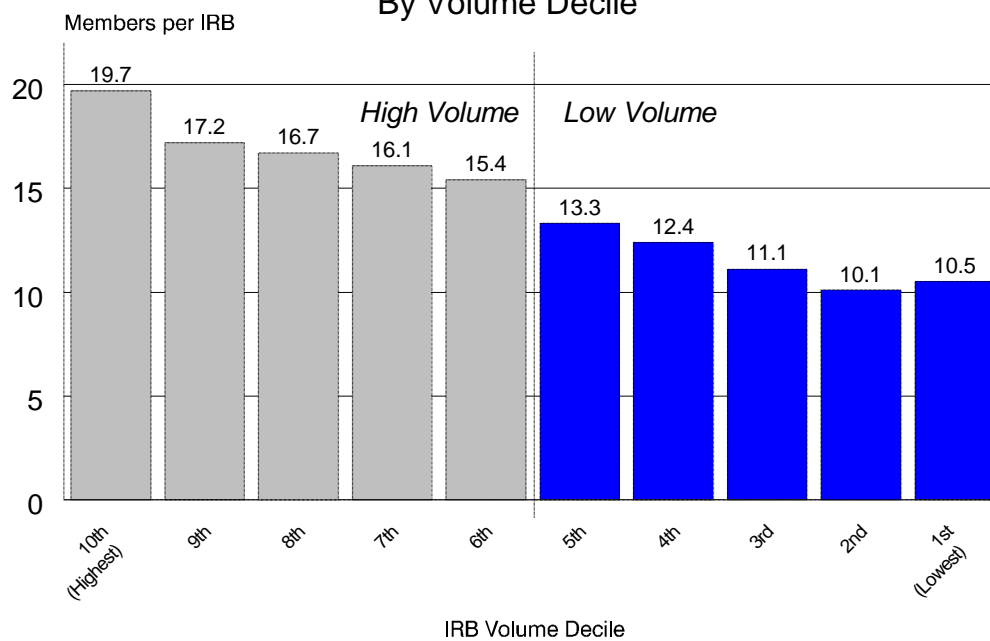
Source: NIH OPRR Records (n = 491), and IRB Administrator Question B5 (n = 245); NIH Study of Human Subjects Protection

Figure 13
Demographics of IRB Personnel



Source: IRB Chair Questionnaire (n = 394); IRB Administrator Questionnaire (n = 245); IRB Member Questionnaire (n = 435), NIH Study of Human Subjects Protection

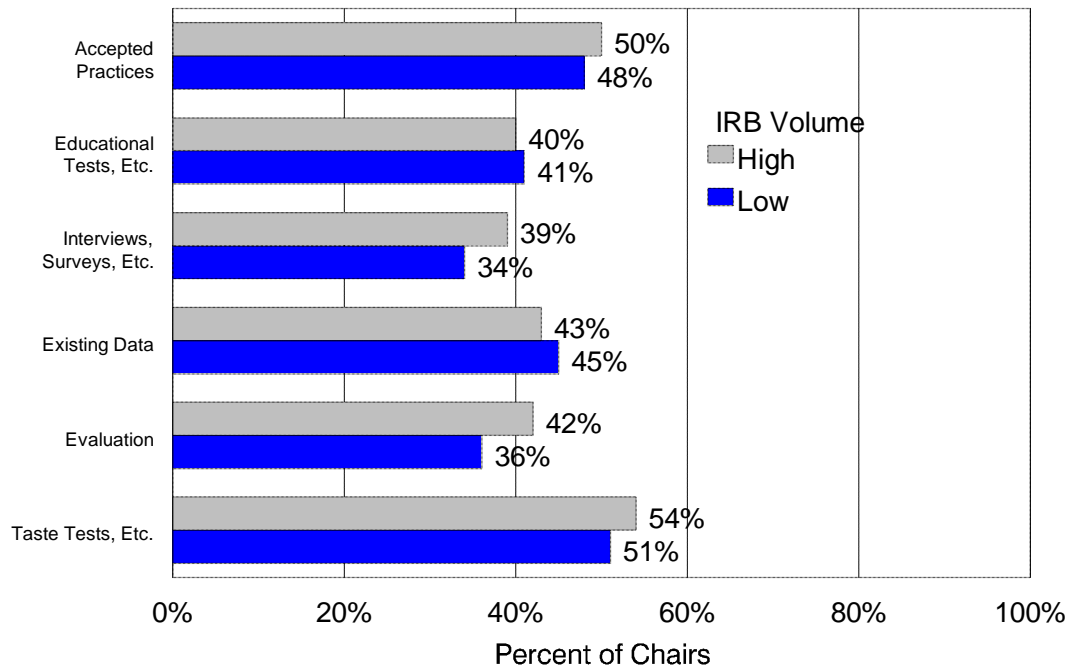
Figure 14
Average Number of Members Per IRB
By Volume Decile



Source: NIH OPRR Records Data (n = 491 IRBs), NIH Study of Human Subjects Protection

Figure 15

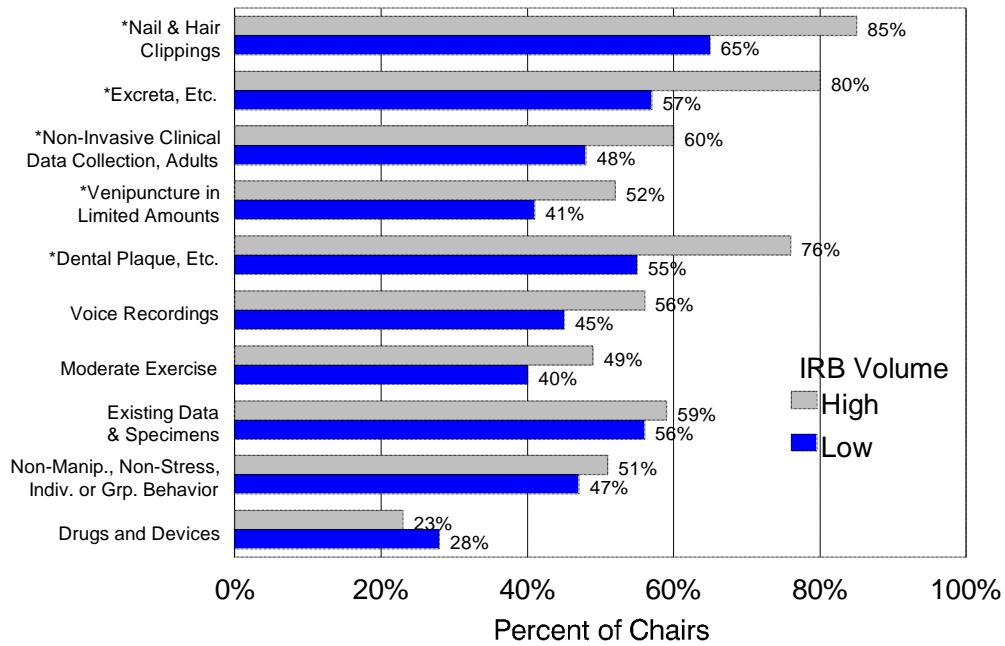
**Standard Practice Was Exemption for Exemptible Research
by Category and IRB Volume**



Source: IRB Chair Question C21 (n = 394), NIH Study of Human Subjects Protection

Figure 16

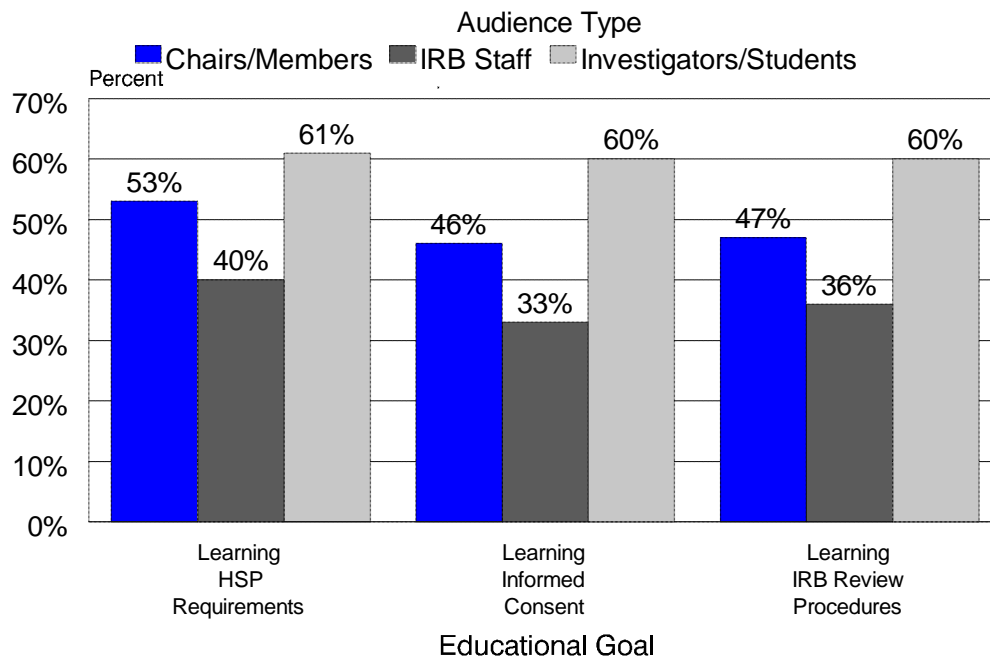
**Standard Practice Was Expedited Review of Expeditable Research
by Category and IRB Volume**



Source: IRB Chair Question C22 (n = 394), NIH Study of Human Subjects Protection

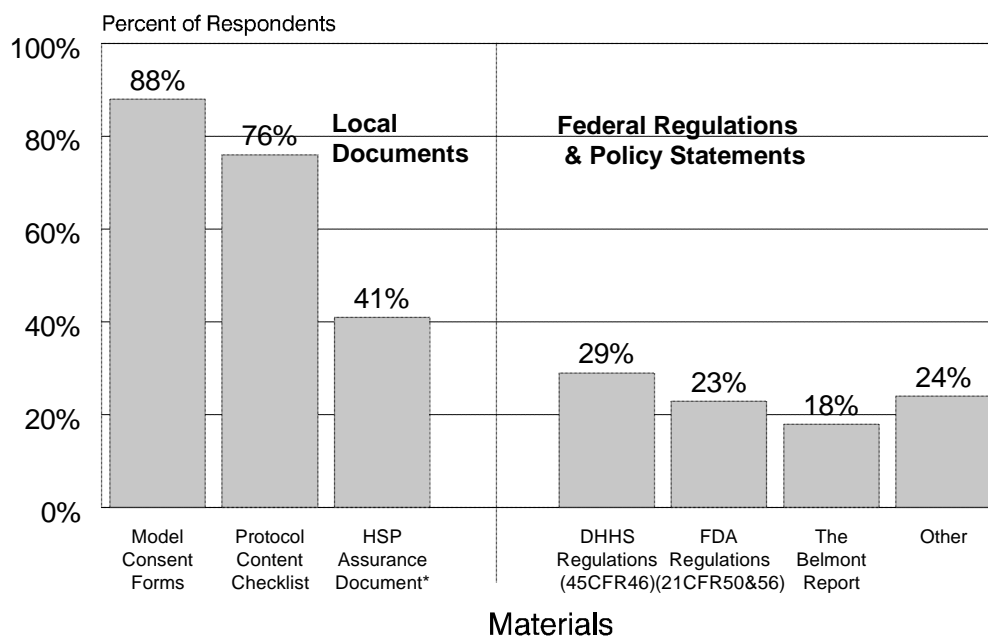
* denotes statistically significant differences at the .05 level

Figure 17
Percent of IRBs Offering Educational Sessions
by Educational Goals and Audience Type



Source: Chair Question C3 (n = 394); NIH Study of Human Subjects Protection

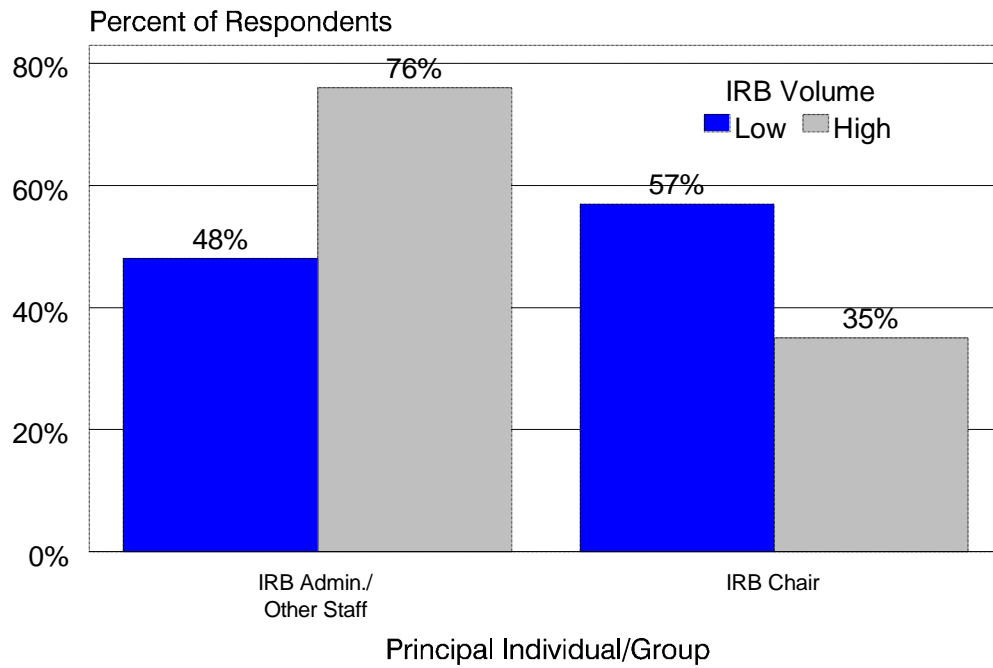
Figure 18
Guidance Materials Routinely Provided



Source: IRB Chair Question C2 (n = 394), NIH Study of Human Subjects Protection

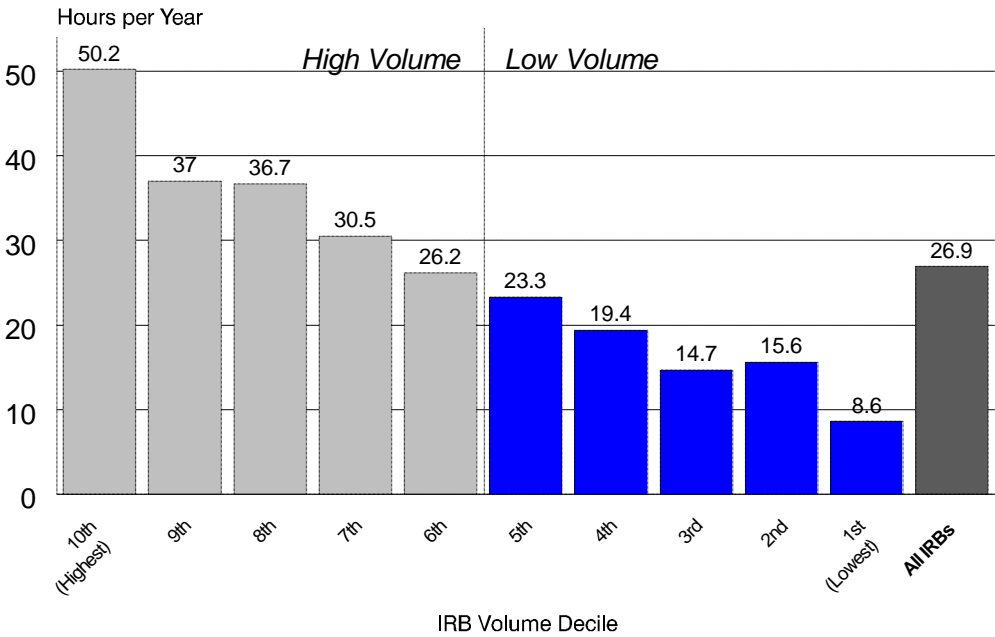
*This document (on file with the Office for Protection from Research Risks at NIH) assures institutional compliance

Figure 19
Who Assigned Primary/Secondary Reviewers for Initial Review



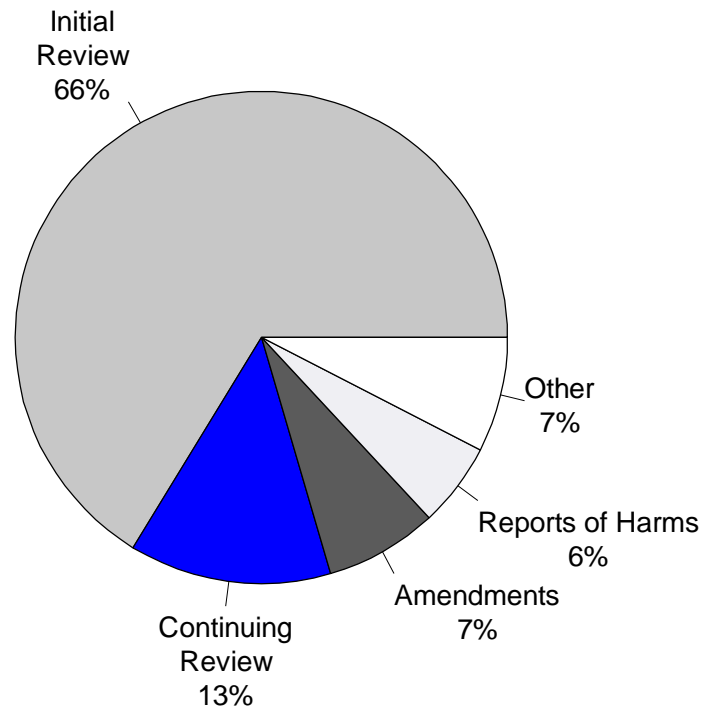
Source: IRB Chair Question C23b (n = 394), NIH Study of Human Subjects Protection

Figure 20
Mean Total Annual Full Board Meeting Time By Volume Decile



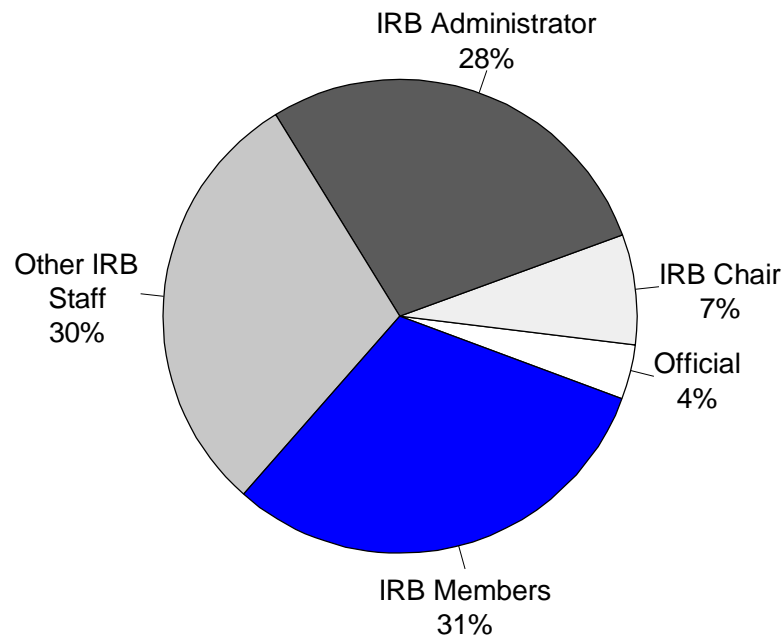
Source: Chair Questions C7-C8 (n = 394), NIH Study of Human Subjects Protection

Figure 21
Distribution of Full Board Meeting Time



Source: IRB Chair Question C11 (n = 394), NIH Study of Human Subjects Protection

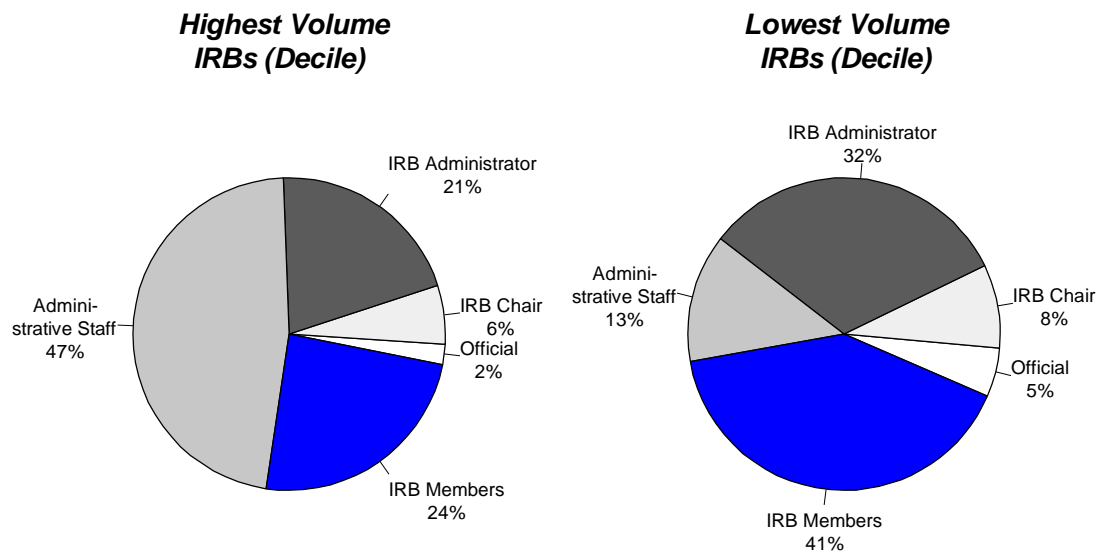
Figure 22
Distribution of Total IRB Effort by Personnel Category



Total Person Hours = 1,670,000

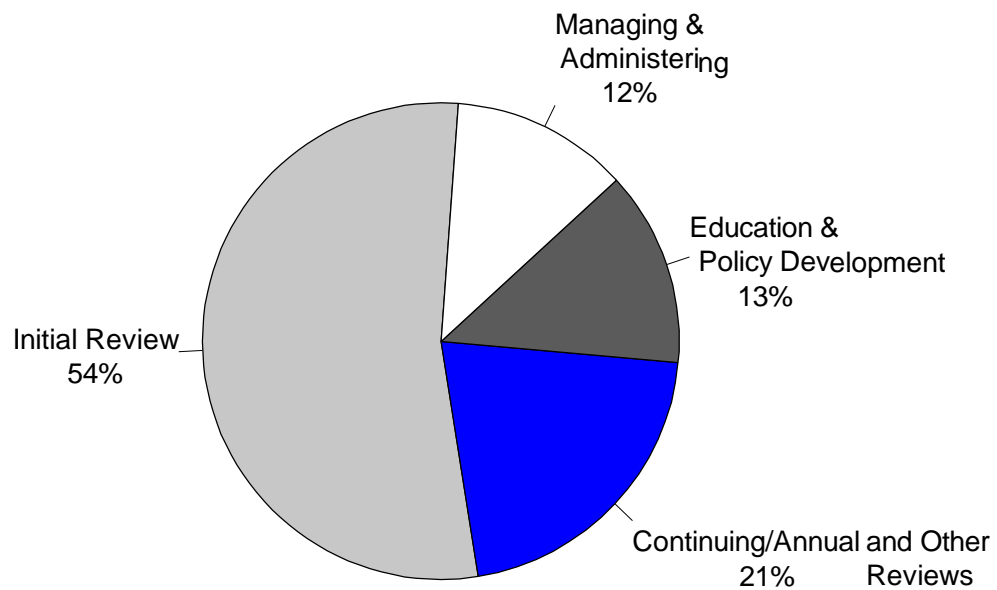
Source: IRB Chair Question A11 (n = 394); IRB Administrator Questions B2 and B5 (n = 245); IRB Member Question B4 (n = 435); and Institution Official Question B3 (n = 400), NIH Study of Human Subjects Protection

Figure 23
Distribution of Total IRB Effort by Personnel Categories
for Highest vs. Lowest Volume Deciles



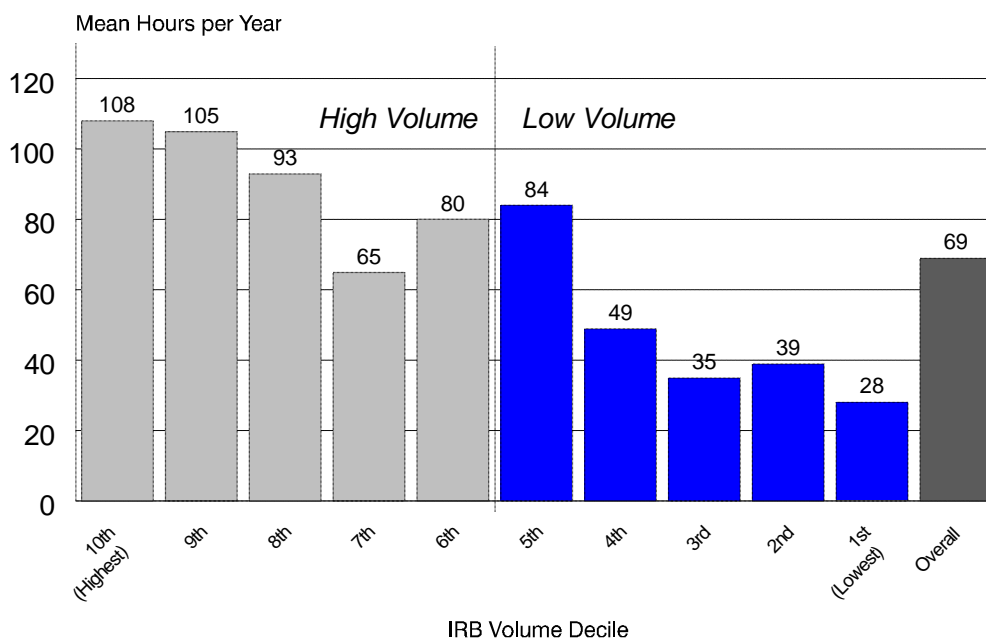
Source: IRB Chair Question A11 (n = 394); IRB Administrator Questions B2 and B5 (n = 245); IRB Member Question B4 (n = 435); and Institution Official Question B3 (n = 400), NIH Study of Human Subjects Protection

Figure 24
Distribution of Chairs' Total Effort by Activity Type



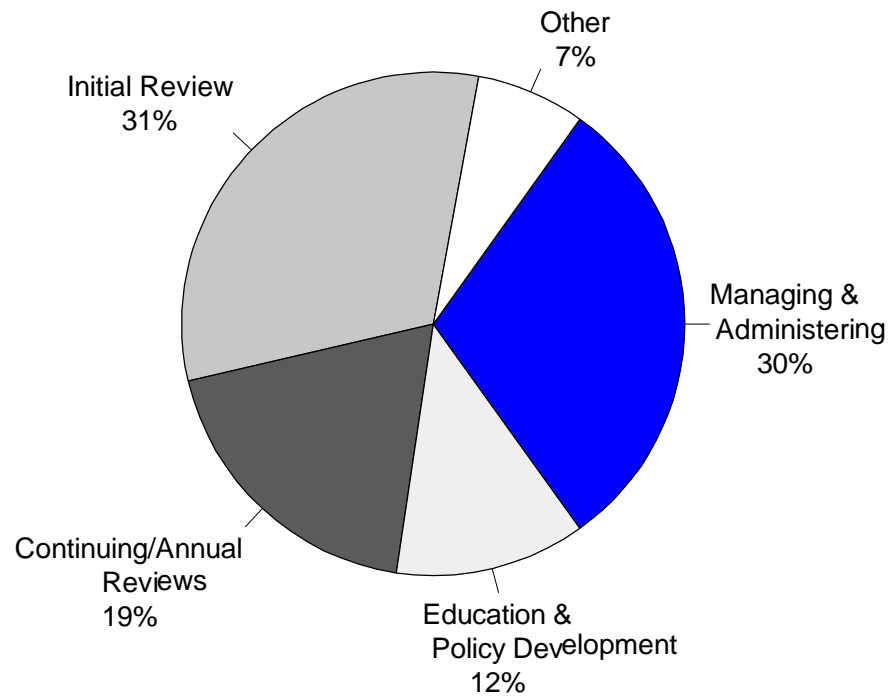
Source: IRB Chair Question A11 (n = 394), NIH Study of Human Subjects Protection

Figure 25
Mean Member Hours Per Year Devoted to IRB Work
By Volume Decile



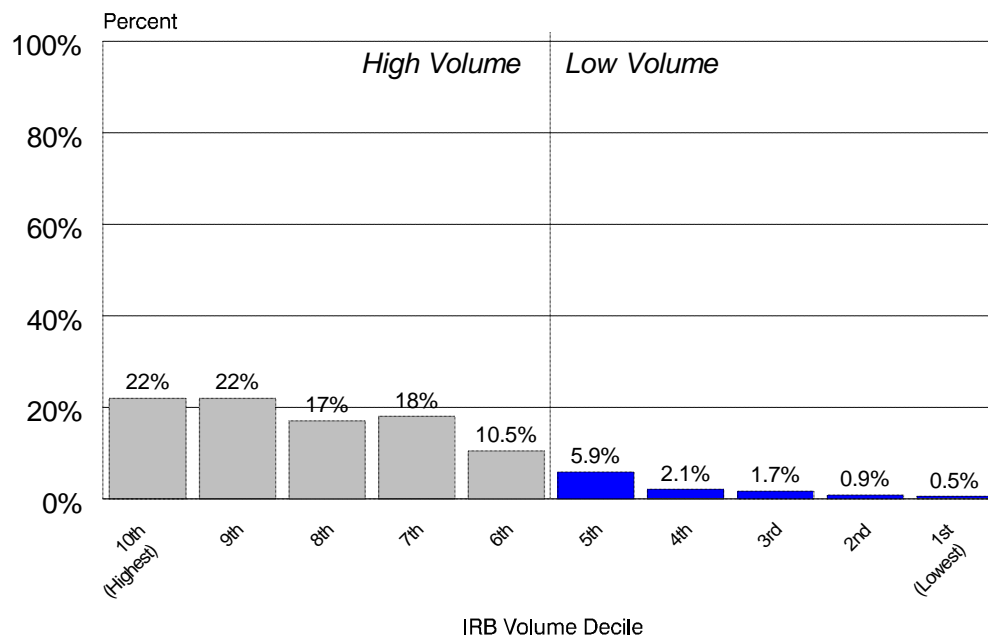
Source: IRB Members Question B4 (n = 435). NIH Study of Human Subjects Protection

Figure 26
Distribution of Administrators' Total Effort by Activity



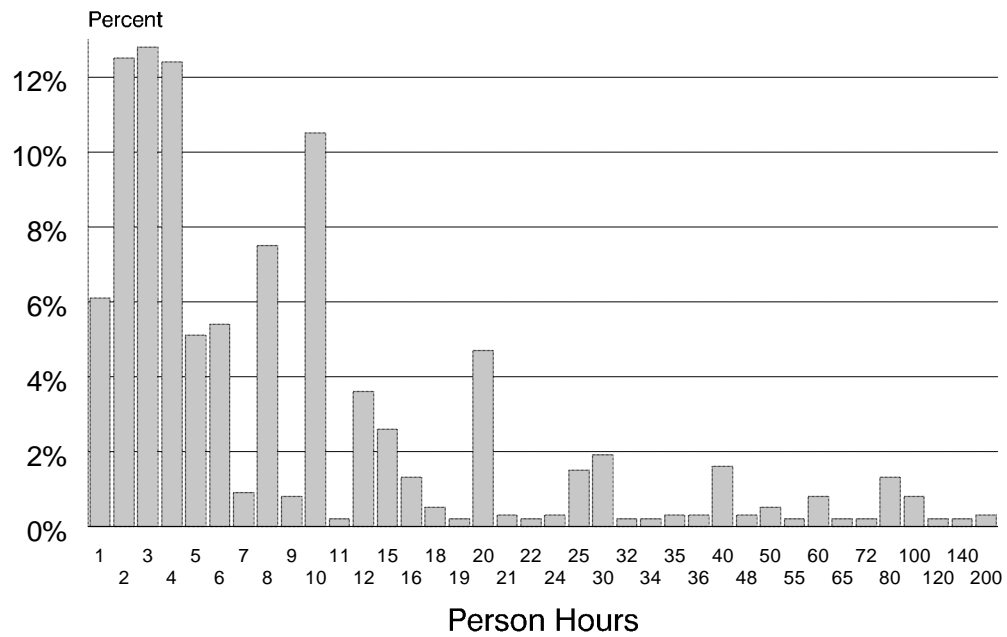
Source: IRB Administrator Question B2 (n = 245), NIH Study of Human Subjects Protection

Figure 27
Distribution of Other Administrative Staff Time By Volume Decile



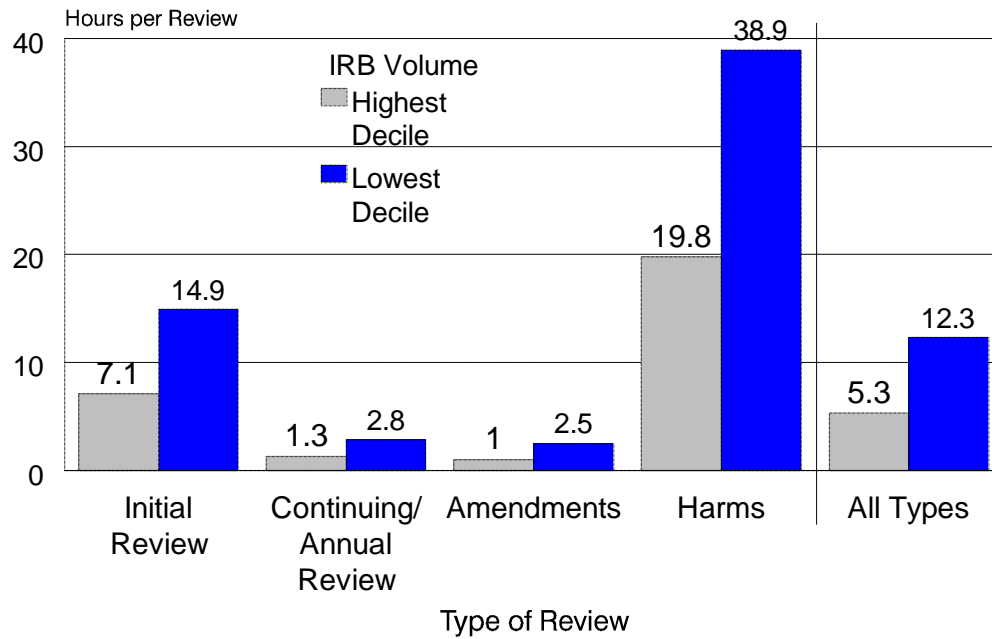
Source: Administrator Question B5 (n = 394), NIH Study of Human Subjects Protection
N = 498,000 person-hours annually

Figure 28
Investigators' Effort on Initial Review



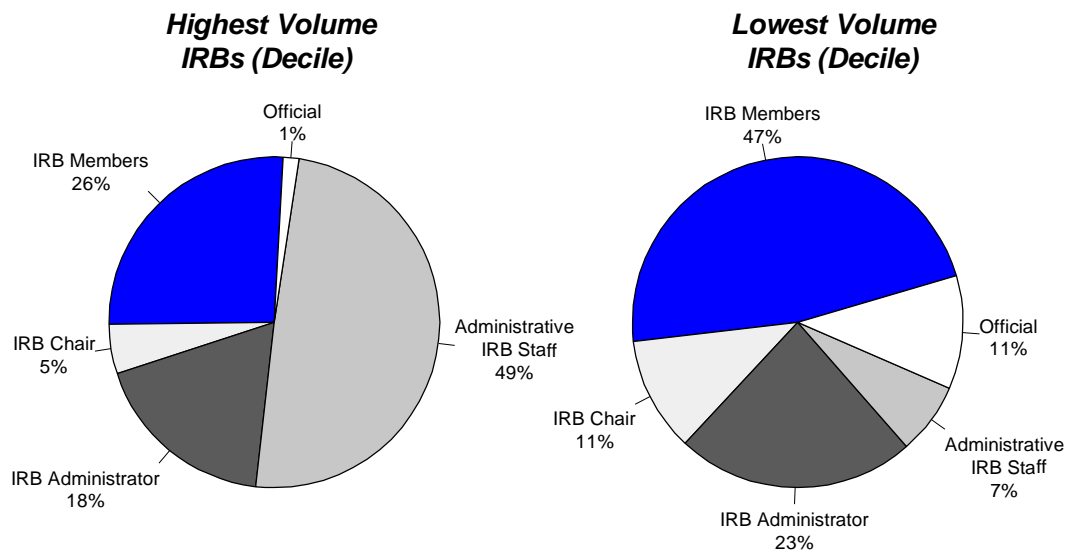
Source: Investigator Question B5 (n = 632), NIH Study of Human Subjects Protection

Figure 29
Person-Time per Type of Review for
Highest vs. Lowest Volume Deciles



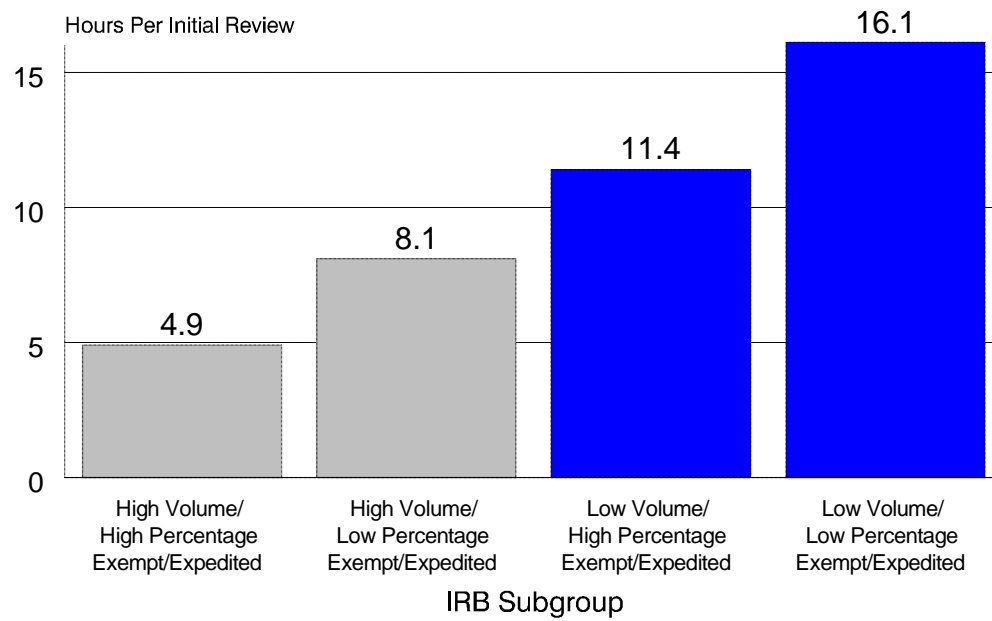
Source: IRB Chair Questionnaire (n = 394); IRB Administrator Questionnaire (n = 245); IRB Member Questionnaire (n = 435); and Institution Official Questionnaire (n = 400), NIH Study of Human Subjects Protection

Figure 30
Distribution of IRB Effort on Initial Review by Personnel Category
by Highest vs. Lowest Volume Deciles

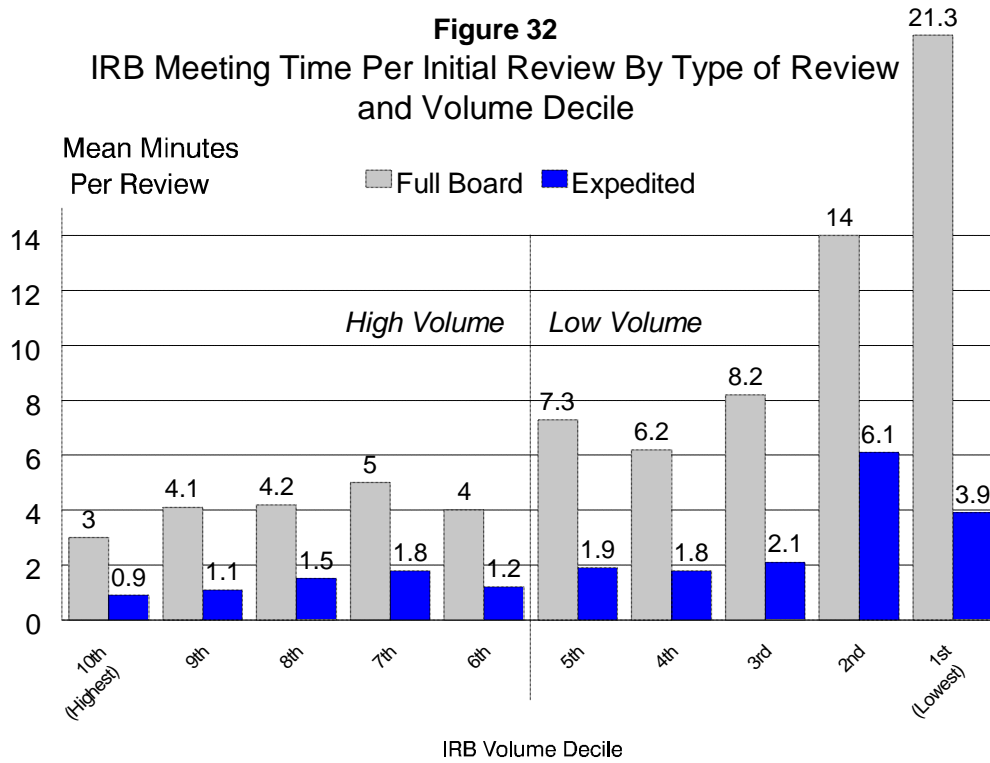


Source: IRB Chair Question A11 (n = 394); IRB Administrator Question B2 and B5 (n = 245); IRB Member Question B4 (n = 435); and Institution Official Question B3(n = 400), NIH Study of Human Subjects Protection

Figure 31
Mean Total Hours Per Initial Review by IRB Subgroup

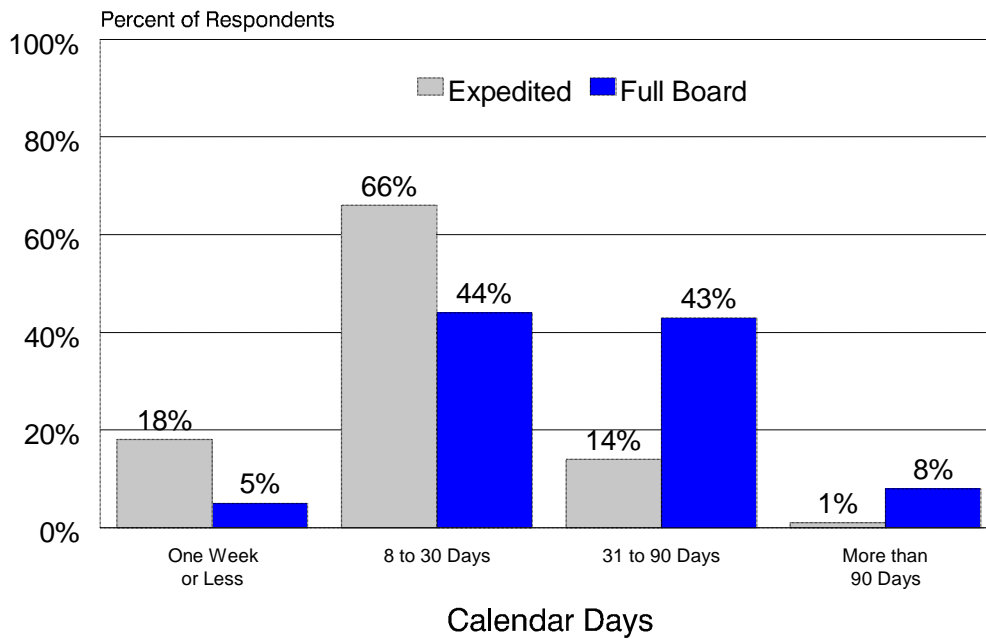


Source: IRB Chair Questionnaire (n = 394); IRB Administrator Questionnaire (n = 245); IRB Member Questionnaire (n = 435); Institution Official Questionnaire (n = 400), NIH Study of Human Subjects Protection



Source: IRB Chair Questions C7 through C12 (n = 394), NIH Study of Human Subjects Protection

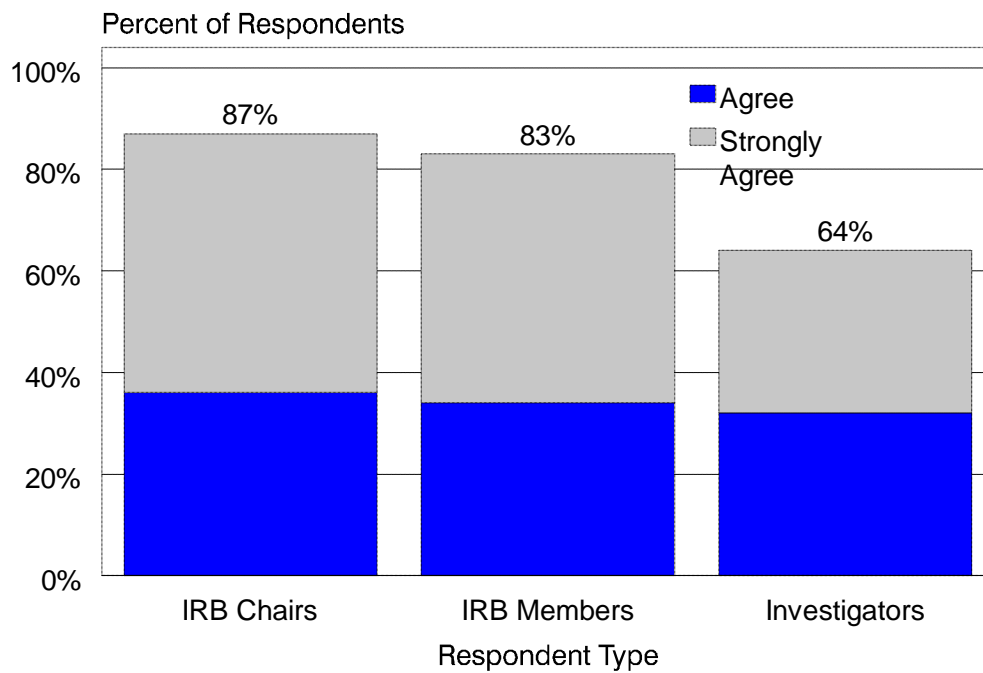
Figure 33
Elapsed Days to Final Disposition
by Type of Initial Review



Source: Investigator Question B4 (n = 632), NIH Study of Human Subjects Protection

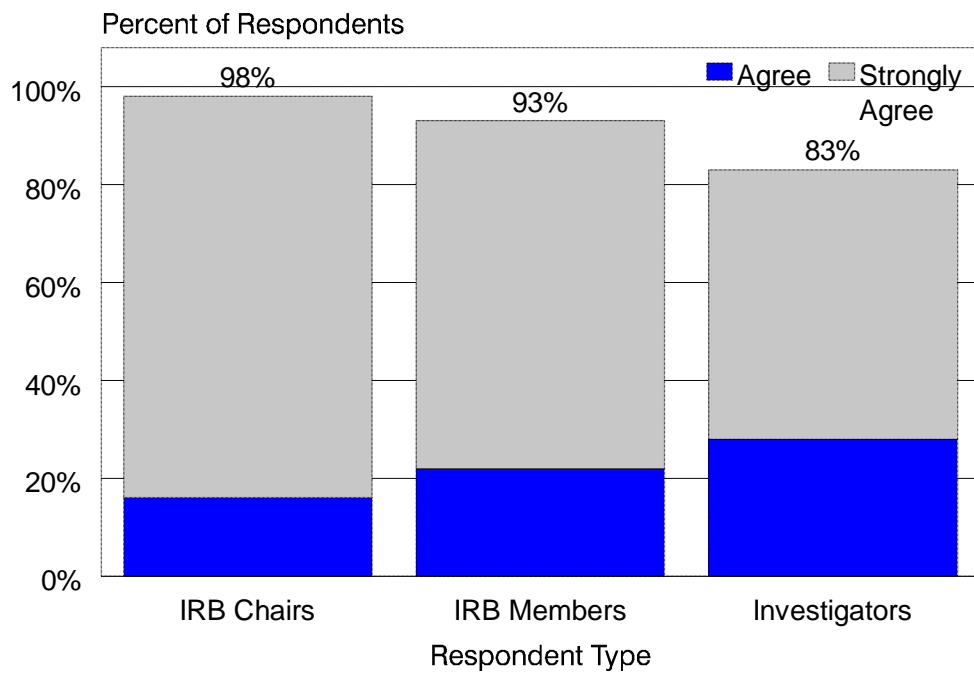
Figure 34

This IRB Runs with Reasonable Efficiency



Source: IRB Chair Question B12 (n = 394); IRB Member Question C6 (n = 435); and Investigator Question C2 (n = 632), NIH Study of Human Subjects Protection

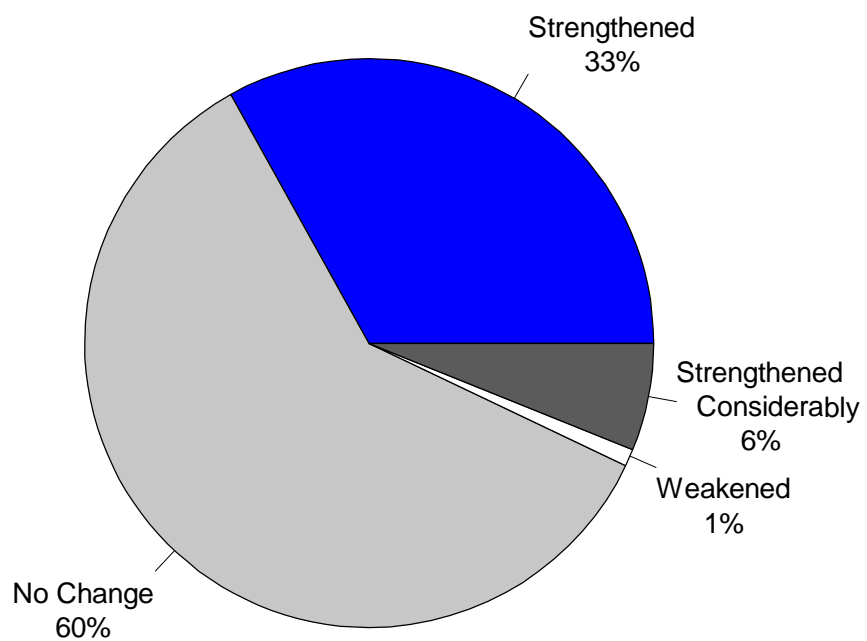
Figure 35
Percentage Agreeing, "This IRB Protects the
Rights and Welfare of Human Subjects"



Source: IRB Chair Question B12 (n = 394); IRB Member Question C6 (n = 435); and Investigator Question C2 (n = 632). NIH Study of Human Subjects Protection

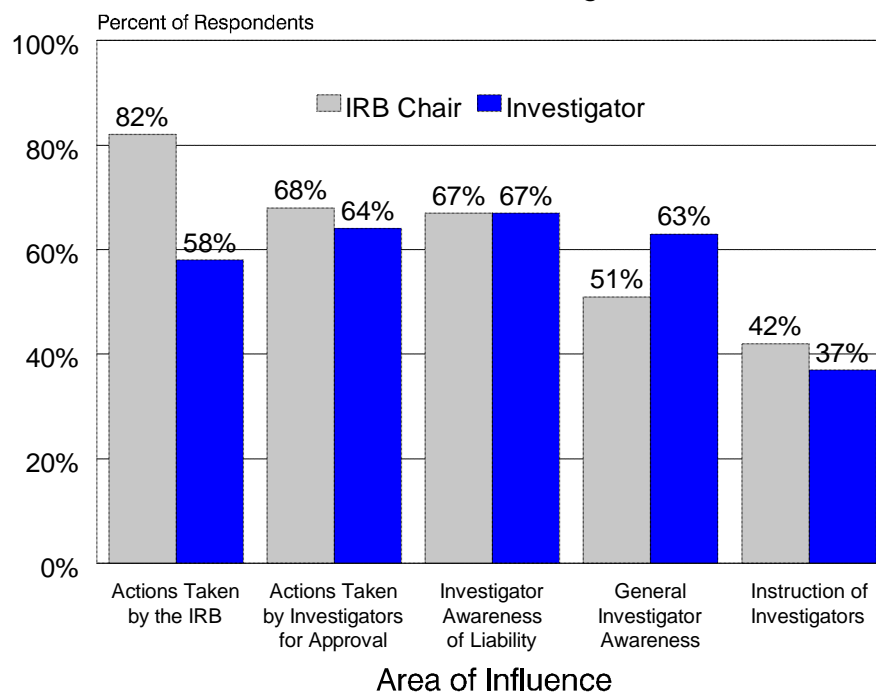
Figure 36

Investigators' Views of Effect of Initial Review on Protocol



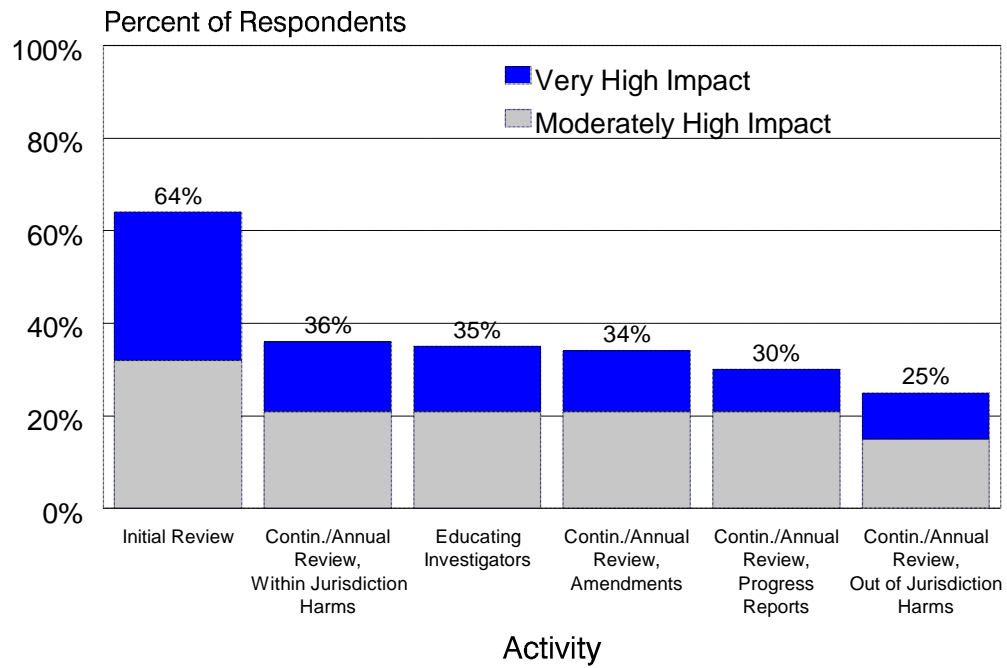
Source: Investigator Question B11 (n = 632), NIH Study of Human Subjects Protection

Figure 37
Ratings of Influences on Protection as High Impact,
Chairs vs. Investigators



Source: IRB Chair Question B11 (n = 394); Investigator Question C5 (n = 632), NIH Study of Human Subjects Protection

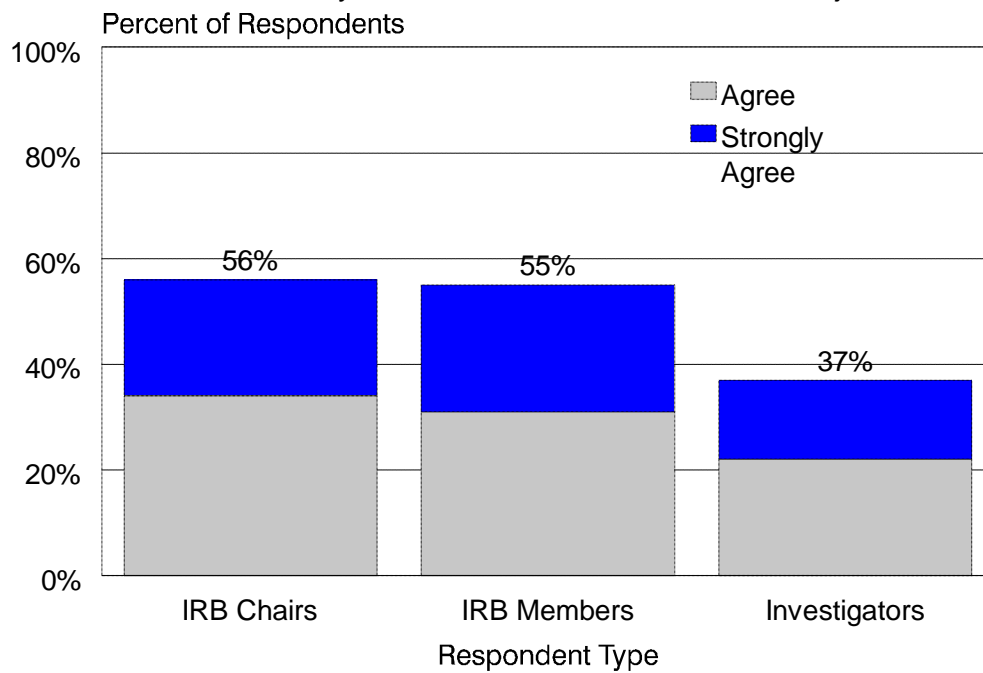
Figure 38
Investigators' Views of IRB Activity
Impact on Protection



Source: Investigator Question C1 (n = 632), NIH Study of Human Subjects Protection

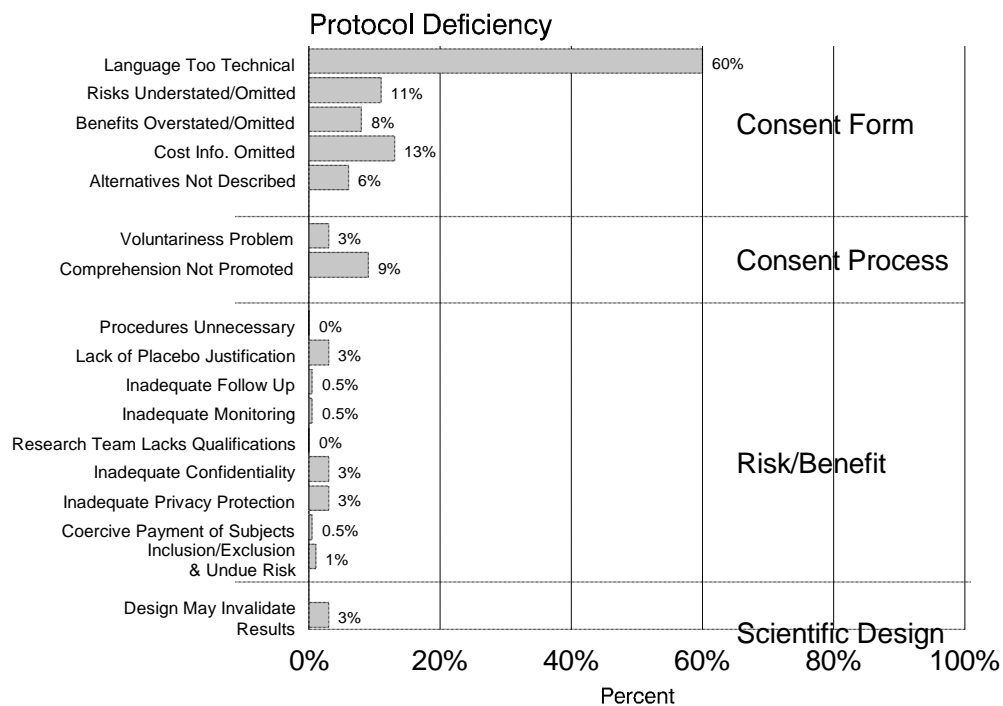
Figure 39

Percentage Agreeing, "This IRB's Reviews Improve the Scientific Quality of Research Done on Human Subjects"



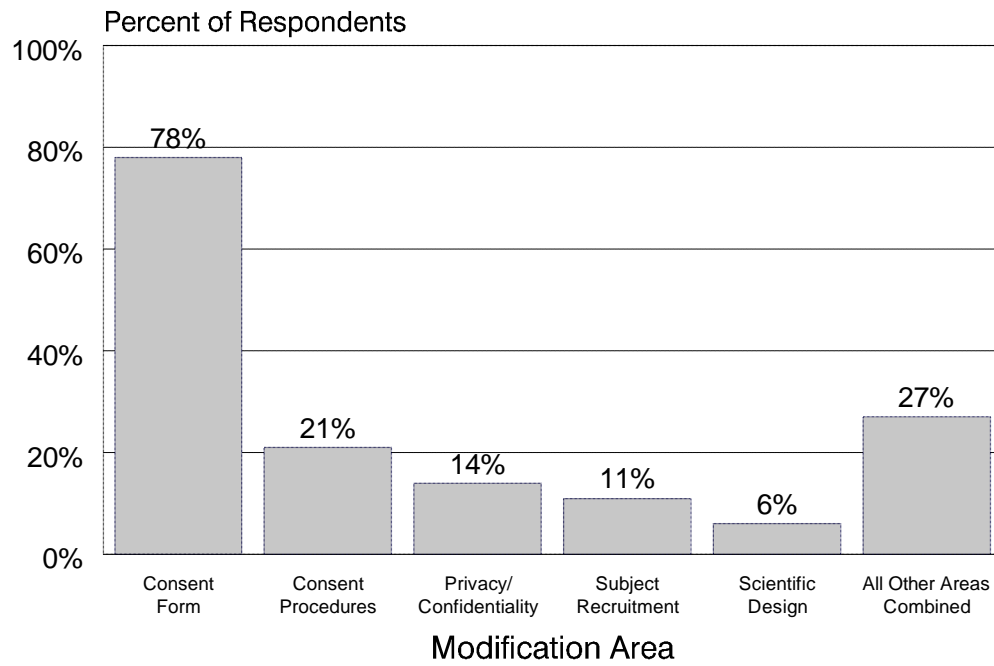
Source: IRB Chair Question B12 (n = 394); IRB Member Question C6 (n = 435); and Investigator Question C2 (n = 632), NIH Study of Human Subjects Protection

Figure 40
Deficiencies Often in Protocols Submitted to the IRB for Review



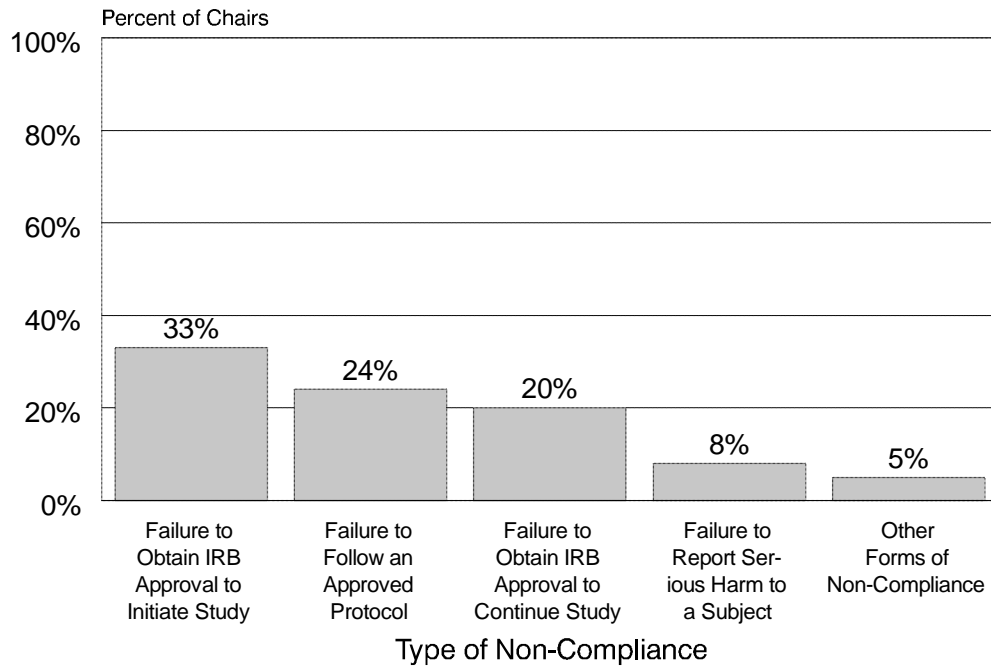
Source: IRB Chair Question C17 (n = 394); NIH Study of Human Subjects Protection

Figure 41
Investigator Reports of Most Common Protocol Modifications



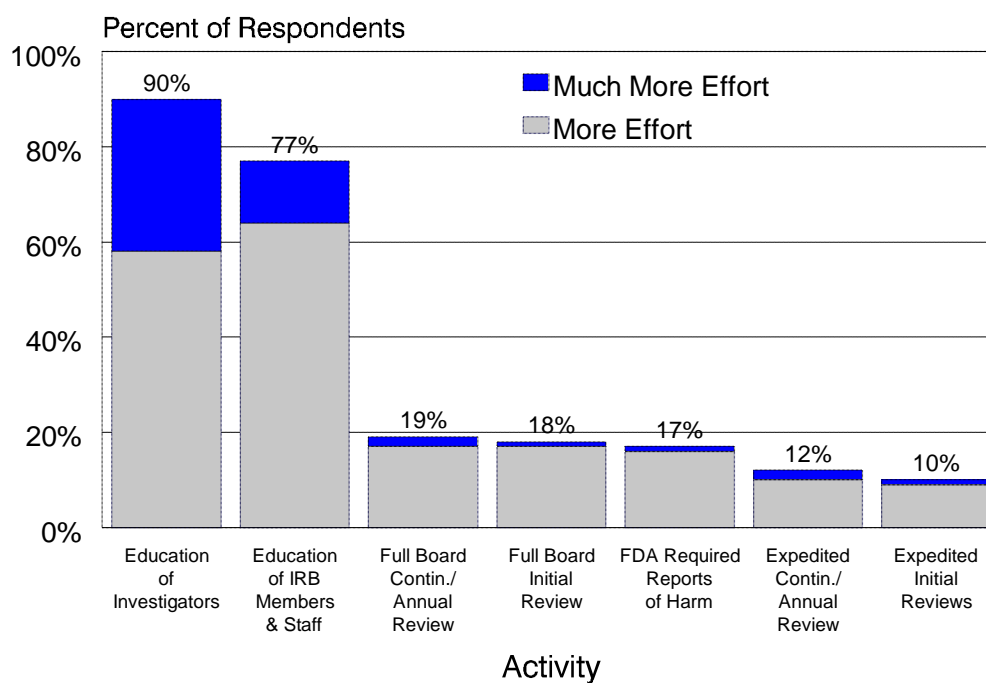
Source: Investigator Question B10 (n = 255), NIH Study of Human Subjects Protection

Figure 42
Percentage of Chairs Reporting Serious Investigator Non-Compliance
by Type of Non-Compliance



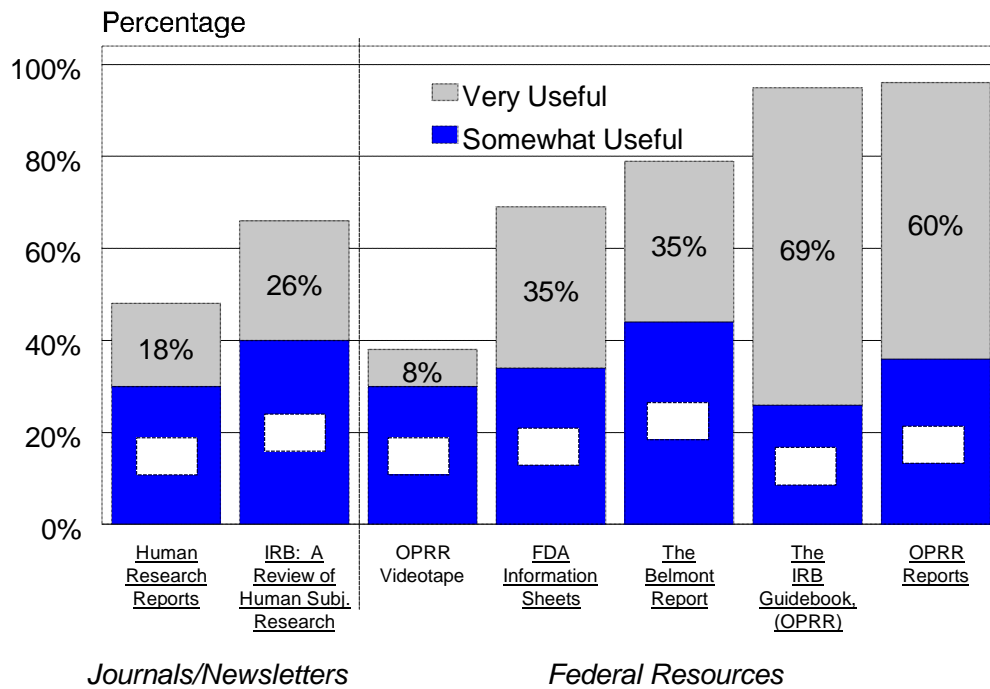
Source: IRB Chair Question C36 (n = 394), NIH Study of Human Subjects Protection

Figure 43
Chairs' Views on Needed Changes in IRB Effort



Source: IRB Chair Question B2 (n = 394), NIH Study of Human Subjects Protection

Figure 44
Chairs Rating Usefulness of Resource/Reference Items



Source: IRB Chair Question A9 (n = 394). NIH Study of Human Subjects Protection